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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,352	09/10/2001	Martin John Glenton Hughes	GJE-70	7295

7590 03/20/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/20/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,352

Applicant(s)

HUGHES ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/21/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-23, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 6) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

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DETAILED ACTION

1. The response to the restriction filed 1/21/03 has been entered into the record. Claims 12-30 are pending.

Election

2. Applicant's election Group V, claims 24-28 with respect to SEQ ID NO: 23 drawn to a method for prevention or treatment of bacterial infection with traverse in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the search and examination of the claims directed to polynucleotides, polypeptides, vaccines and methods utilizing the recited polypeptides should be examined under PCT rule 13.1 and 13.3 since there is a unity of invention present. Further, applicant claims that during international phase, the PCT application corresponding to the subject U.S. National application was determined to have unity of invention with respect to different uses of the genes.

This is not found persuasive because the examiner believes that the application has been filed under 35 U.S.C. 371, Lack of Unity practice is being followed as per PCT rule 13.2.

It is the position of the Office that the expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Specifically, the art teaches pho 2-2 was a putative homologue of MalK and other ABC type transporters (see example 7 of the Specification). Further, one pho3-1 homologue from B. subtilis was known (see example 11 of the Specification) and appear to be surface proteins. Therefore, Claim 12 does not constitute a special technical feature by definition. Therefore, unity of invention is lacking.

Further, Applicants indicate that with respect to the species election, they elect SEQ ID NO: 23. It is specifically noted, that a species election was not imposed. Each of the recited sequences was deemed patentably distinct from each other and applicants were required to

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elect a single product for examination on the merits. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 12-23 and 29-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Priority

4. This application 09/868,352 is a national stage entry of PCT/GB99/04377 International Filing Date: 12/22/1999, which claims priority to

UNITED KINGDOM 9828359.1 12/22/1998
UNITED KINGDOM 9828353.4 12/22/1998
UNITED KINGDOM 9828352.6 12/22/1998
UNITED KINGDOM 9828355.9 12/22/1998
UNITED KINGDOM 9828354.2 12/22/1998
UNITED KINGDOM 9828349.2 12/22/1998
UNITED KINGDOM 9828345.0 12/22/1998
UNITED KINGDOM 9828350.0 12/22/1998
UNITED KINGDOM 9828357.5 12/22/1998
UNITED KINGDOM 9828356.7 12/22/1998
UNITED KINGDOM 9900084.6 01/04/1999
UNITED KINGDOM 9900086.1 01/04/1999
UNITED KINGDOM 9900082.0 01/04/1999
UNITED KINGDOM 9900085.3 01/04/1999
UNITED KINGDOM 9900083.8 01/04/1999
UNITED KINGDOM 9901916.8 01/28/1999
UNITED KINGDOM 9901922.6 01/28/1999

5. According to the priority statement as it appears above, priority is being claimed to a large number of foreign applications. These applications appear to be drawn to unrelated subject matter and are either not available for consideration or for which consideration to determine support for the instantly claimed subject matter would require an undue burden. Accordingly, the subject matter defined in the elected claims 24-28, drawn to SEQ ID NO: 23 have an effective filing date of 12/22/1999, that of the PCT/GB99/04377 application.

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Applicants are requested to provide the serial number and specific page numbers of any foreign application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled of prior to 12/22/1999.

Drawings

6. No Drawings have been filed in this application

Information Disclosure Statement

7. Information Disclosure Statement filed on 9/17/01 (Paper # 6) is acknowledged and a signed copy is attached to this Office action.

Specification - Informalities

8. Applicant should follow the direction or order or arrangement in framing the specification as provided in 37 CFR 1.77(b) since this is a utility application filed in USA.

For example: Claims should begin with "I claim" or "we claim" or "What is claimed is".

It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/GB99/04377, a copy of the abstract will be inserted in to the specification.

There are no line numbers in the specification pages.

Applicant is advised to restrict the claims 24-28 to pho 3-1, SEQID.NO: 23 since this is an elected invention.

Claim Rejections - 35 U.S. C. § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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10. Claims 24-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification broadly describes as part of the invention polynucleotide sequences comprising the genes pho1-13, pho3-21, pho2-15, pho3-18, pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29 encoding the polypeptide of: 2, 4, 6, 8, 10, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35 from Group B streptococcus. The actual biological function of the polynucleotide sequences comprising the genes pho1-13, pho3-21, pho2-15, pho3-18, pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29 encoding the polypeptide of: 2, 4, 6, 8, 10, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35 is not set forth in this specification. Therefore, a method for treatment or prevention associated with any and all bacterial infections using these broadly described polynucleotide sequences comprising homologue or a functional fragment of one of said pho3-1 Group B streptococcus gene also does not meet the guidelines on written description.

Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the encoding sequence by use of language in which a specified fragment of said genes and immunogenic homologs that correspond to sequences from other species of Bacteria, mutated sequences, allelic variants and comprising the genes pho1-13, pho3-21, pho2-15, pho3-18,

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pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29 or nucleic acids encoding the polypeptide of : 2, 4, 6, 8, 10, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35. None of these sequences and the method using these sequence meets the written description provision of 35 U.S.C. 112, first paragraph. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See *Vas-Cath* at page 1116.).

The specification only discloses a polynucleotide sequences encoding GBS (Group B *Streptococcus*) M732 the polypeptide of: 2, 4, 6, 8, 10, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35. The specification fails to teach a single fragment or homolog of a polypeptide sequence of SEQ ID NO: 23 and a method for treatment or prevention associated with any and all bacterial infections using fragment or homolog of a polypeptide sequence of SEQ ID NO: 23. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number fragments or homologue polypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed in claims 24-28.

11. Claims 24-28 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification provides no information on the immunogenicity of protein encoded by the nucleic acid, the claimed fragments, the variants or the ability of such to protect from bacterial infections. The specification fails to teach that the claimed nucleic acids encoding the polypeptide or fragments are capable of generating a humoral or cellular immune response. The specification also fails to teach that the immune/antibody response to the polypeptide produced by the nucleic acid, alone or in combination with adjuvants or carriers provides for a protection against infection in any acceptable animal model. The specification fails to teach any immune response generated by means of a nucleic acid encoding --. It is well recognized in the art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach even one of the claimed polynucleotide encoding polypeptides or fragments thereof alone or in combination with other antigens does in fact confer protection from infection, as is requisite of a method of treatment or prevention. In the absence of a teaching of the claimed polynucleotide encoding the peptide as set forth in SEQ.ID.NO: 23 can generate an immune response and that immune response is effective in prevention or treatment of any and all bacterial infections, the specification is not enabled for a method of treatment or prevention of any and all bacterial infections with the claimed fragments or homologs of peptide as set forth in SEQ.ID.NO: 23. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

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12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in the recitation of " pho1-13, pho3-21, pho2-15, pho3-18, pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29". These relative terms in claims renders the claim indefinite. The recitation of the terms pho1-13, pho3-21, pho2-15, pho3-18, pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29 appear to be lab designations. Since this is merely a lab designation, such designation change from lab to lab or the same designation can be used for totally different genes. Therefore, recitation of pho1-13, pho3-21, pho2-15, pho3-18, pho3-33, pho3-3 pho3-17, pho2-2, pho1-5, pho3-1, pho3-23, pho3-50, pho1-14, pho2-10, pho3-14, pho3-24, pho3-29 must be designated or identified by Sequence identification numbers or ATCC numbers.

Claim 24 is rejected as being vague because the claim is drawn to a method for treatment or prevention of a condition associated with bacterial infection. In general prevention means prophylactic. Therefore, recitation of " a method for the treatment of a disease associated with bacterial infection ---- or a method for the prevention of bacterial infection ---" is appropriate.

Claims 24-28 are indefinite as depending upon non-elected subject matter and applicant is advised to amend the claims to restrict to SEQ.ID.NO: 23. Correction is required.

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Status of Claims

14. No claims are allowed.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

3/18/03


**LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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